

REMARKS

Applicants have received and carefully reviewed the Office Action mailed May 14, 2009. Currently, claims 16-20 and 22-36 remain pending. Claims 16-20 and 22-36 have been rejected. With this Amendment, claims 16, 29, and 33 have been amended, and claim 34 has been cancelled. Favorable consideration of the following remarks is respectfully requested.

Drawings

On page 2 of the Office Action, the drawings were objected to under 37 C.F.R. §1.83(a) as failing to show every feature of the invention specified in the claims. In particular, the limitation “wherein the distal shaft portion has fewer axial members than the proximal shaft portion” of claim 20 was objected to as not being shown in the drawings. Applicants respectfully disagree. Applicants note that Figure 4, as amended with the Amendment submitted July 28, 2008, shows this limitation. In particular, Figure 4 includes reference numeral 14, corresponding to the proximal region, and reference numeral 16, corresponding to the distal region. As can be clearly seen in Figure 4, the proximal region 14 shows two groups of axial members 34 and the distal region 16 shows one group of axial members 34. This clearly shows the distal shaft portion having fewer axial members than the proximal shaft portion. Therefore, the drawings are believed to show each and every feature of the invention specified in the claims. Withdrawal of the rejection is respectfully requested. Further, as noted in the Amendment filed March 25, 2009, Applicants believe that the Amendment filed July 28, 2008 was entered as it contained no amendments to the claims and Applicants will continue to assume that the Amendment was entered unless the Applicants are notified that it was not entered.

Claim Rejections under 35 U.S.C. §112

On page 3 of the Office Action, claim 33 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Office Action indicated that “the reinforcement layer is free of crossover points having the first helical member and the second helical member on the same side of the one or more axially extending member” is vague and unclear. While Applicants believe that this phrase is clear, in the spirit of cooperation, claim

33 has been amended to recite "the reinforcement layer is free of crossover points having the first helical member and the second helical member both inside of the one or more axially extending members or both outside of the one or more axially extending members". As such, claim 33 is believed to be clear and withdrawal of the rejection is respectfully requested.

Claim Rejections under 35 U.S.C. §103

On page 3 of the Final Office Action, claims 16-20, 22, 24 and 29-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. (U.S. Patent No. 5,057,092) in view of Kaye (U.S. Patent No. 4,191,219). After careful review, Applicants respectfully traverse this rejection.

Turning to claim 16, which recites:

16. An intravascular catheter comprising an elongate shaft including an inner polymer layer defining a lumen of the elongate shaft, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points such that the lumen of the elongate shaft and an outer surface of the outer polymer layer are free from radial protrusions.

Nowhere do Webster, Jr. or Kaye disclose many elements of claim 16, including for example, "the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points such that the lumen of the elongate shaft and an outer surface of the outer polymer layer are free from radial protrusions".

Instead, Webster, Jr. discloses an intravascular catheter including an elongated catheter body having a flexible plastic inner wall 22, a braided reinforcing mesh 24 surrounding the inner wall 22, and a flexible plastic outer wall 30 surrounding the reinforcing mesh 24. The braided reinforcing mesh 24 includes a plurality of interwoven helical members 26. Webster, Jr. teaches that, typically, half of the interwoven helical members 26 extend in one direction and the other half of interwoven helical members 26 extend in the counter direction. In addition, the braided

reinforcing mesh 24 includes longitudinal warp members 28. However, the longitudinal warp members 28 are not disposed between the first and second helical members 26 at each of the plurality of crossover points. Instead, at numerous crossover points, both the first and second helical members 26 are on the same side of the longitudinal warp members 28. See, for example, Figure 2. As such, Webster, Jr. does not teach or suggest the longitudinal warp members 28 disposed between the first and second helical members at each of the plurality of crossover points.

Kaye disclose a triaxial fabric for use as a needlepoint canvas with the yarns forming the fabric being defined by three sets of yarn courses with the courses within each set being parallel. The courses of each set are angular to the courses of the other two sets, usually at a 60-degree angle with the courses from all three sets commonly intersecting at a plurality of points in a repetitive pattern over the fabric. (See Abstract). Applicants respectfully assert that fabric for a needlepoint canvas formed of yarn as taught by Kaye is clearly non-analogous art.

As the Examiner is aware, a *prima facie* case of obviousness is established "when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Application of Rinehart*, 531 F.2d 1048, 1052 (CCPA, 1976). "The reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). In *Application of Wood*, the court presumes, when determining obviousness, "full knowledge by the inventor of all the prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved." 599 F.2d 1032, 1036 (CCPA, 1979).

Clearly, fabric for a needlepoint canvas is not in Applicants' field of endeavor. Applicants' field of endeavor, as evidenced by the Field of Invention on page 1 of the present application, is intravascular catheters or, more specifically, intravascular catheters having a braid reinforcement. As Kaye is not in Applicants' field of endeavor, it must be reasonably pertinent to the particular problem with which the inventor was involved. Applicants respectfully assert that yarn for a needlepoint fabric is clearly not reasonably pertinent to axial members for a braided reinforcement layer disposed between an inner and outer polymer layer and that a person

of skill in the art would not look to needlepoint fabric when designing medical devices. Thus, Applicants respectfully assert that Kaye is non-analogous art and cannot be relied upon to establish a *prima facie* case of obviousness.

However, if Kaye is somehow considered analogous art (which Applicants believe is not), Applicants respectfully assert that Webster, Jr. teaches away from any combination with Kaye. Applicants note that MPEP § 2141.02 states “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)”. Further, “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)”. (MPEP § 2145). As noted above, Kaye discloses setting the angle of the threads (for example, D, E, F, G, H, I, J, K shown in Figures 2 and 3) at a 60-degree angle relative to the warp courses (for example, C shown in Figures 2 and 3) for the weave. However, column 2, lines 44-53 of Webster, Jr. states:

The tightness or angle of the helical members 26 to the longitudinal members 28 is not critical but is preferably from about 30° to about 45°. An angle less than about 30° is not preferred because as the braid angle becomes smaller, the catheter tends to buckle when it is bent. Further, such catheters tend not to transmit torque around corners as well as catheters having higher braid angles. Braid angles greater than 45° are not preferred because they do not appear to offer any advantage and are less economical.

(Emphasis added). From this, Webster Jr. teaches away from braid angles greater than 45 degrees. As such, one of skill in the art would not combine the weave pattern of Kaye having 60-degree angles with the teachings of Webster, Jr. that teaches patterns of 45 degrees or less. Thus, Applicants respectfully assert that Webster, Jr. teaches away from any combination with Kaye and, as such, the asserted combination is clearly improper.

Further, it is axiomatic that “because they can be” clearly fails to establish a proper *prima facie* case of obviousness. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int’l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness”.

(Emphasis added) (see page 14 of the April 30, 2007 decision). The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 decision). It appears that the rejection has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. The reasoning provided in the Office Action to support the legal conclusion of obviousness is that “it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with an interwoven cross construction, as taught by Kaye, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility”. However, these reasons appear to come directly from Applicants’ own specification, see for example, paragraphs 13, 36-41, and 47. Applicants note MPEP § 2142 states:

Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Applicants submit that the only motivation or reason for combining Webster, Jr. and Kaye in the manner suggested by the Office Action comes from Applicants’ own specification, which is clearly improper. Therefore, for at least these reasons, claim 16 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 17-20, 22 and 24, which depend from claim 16 and which include additional distinguishing features, are believed to be patentable over Webster, Jr. and Kaye.

Turning to claim 29, which recites:

29. A method of making a portion of a shaft of an intravascular catheter, the method comprising the steps of:

providing a carrier including an elongate tube having an inner polymer layer disposed thereon;

braiding a first helical member and a second helical member about [[a]] the carrier forming a plurality of crossover points such that a plurality of axial members are disposed between the first and second helical members at each of the plurality of crossover points to form a reinforcement layer that is free of radial protrusions; and

disposing an outer polymer layer over the reinforcement layer.

Nowhere do Webster, Jr. and Kaye disclose many elements of claim 29, including for example, the specific method step of "braiding a first helical member and a second helical member about the carrier forming a plurality of crossover points such that a plurality of axial members are disposed between the first and second helical members at each of the plurality of crossover points to form a reinforcement layer that is free of radial protrusions". Therefore, for similar reasons discussed above, as well as others, claim 29 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 30-32, which depend from claim 29 and which include additional distinguishing features, are believed to be patentable over Webster Jr. and Kaye.

Turning to claim 33, which recites:

33. An intravascular catheter comprising an elongate shaft having an inner polymer layer, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and one or more axially extending members disposed between the first helical member and the second helical member so that the reinforcement layer is free of crossover points having the first helical member and the second helical member both inside of the one or more axially extending members or both outside of the one or more axially extending members such that the reinforcement layer is free of radial protrusions caused by the one or more axial members.

Nowhere do Webster, Jr. and Kaye disclose many elements of claim 33, including for example, the specific method step of "the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and one or more axially extending members disposed between the first helical member and the second helical member so that the reinforcement layer is free of crossover points having the first helical member and the second helical member both inside of the one or more axially extending

members or both outside of the one or more axially extending members such that the reinforcement layer is free of radial protrusions caused by the one or more axial members". Therefore, for similar reasons discussed above, as well as others, claim 33 is believed to be patentable over Webster, Jr. and Kaye. For similar reasons and others, claims 35-36, which depend from claim 33 and which include additional distinguishing features, are believed to be patentable over Webster Jr. and Kaye.

On page 6 of the Office Action, claims 16-20, 22, 24 and 29-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Huppert (U.S. Patent No. 2,114,274). After careful review, Applicants respectfully traverse this rejection.

Huppert discloses a tubular braid for use in the manufacture of hair dressing accessories, such as foundations, curlers, rollers, and the like. As noted above, independent claim 16 recites "an inner polymer layer defining a lumen of the elongate shaft, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer"; independent claim 29 recites "providing a carrier including an elongate tube having an inner polymer layer disposed thereon" and "disposing an outer polymer layer over the reinforcement layer"; and independent claim 33 recites "an inner polymer layer, a reinforcement layer disposed about the inner polymer layer, and an outer polymer layer disposed about the reinforcement layer". Clearly, nowhere does Huppert teach or suggest at least these limitations. Therefore, for at least these reasons, independent claims 16, 29 and 33 are believed to be patentable over Huppert. For similar reasons and others, claims 17-20, 22, 24, 30-32 and 35-36, which depend from one of claims 16, 29, and 33 and which include additional distinguishing features, are believed to be patentable over Huppert.

On page 8 of the Office Action, claims 23 and 25-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. (U.S. Patent No. 5,057,092) in view of Kaye (U.S. Patent No. 4,191,219) or Huppert (U.S. Patent No. 2,114,274) and further in view of Mortier et al. (U.S. Patent No. 5,730,733). After careful review, Applicants respectfully traverse this rejection. As discussed previously, claim 16 is believed to be patentable over Webster, Jr. and Kaye or Huppert, and nothing in Mortier et al. remedies the above-noted shortcomings of Webster, Jr. Therefore, for at least these reasons, claims 23 and 25-28, which depend from claim

16 and which include additional limitations, are believed to be patentable over the cited references.

Double Patenting

On page 9 of the Office Action, claims 16-32 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,709,429. Also on page 9 of the Office Action, claims 16 and 22-30 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11 and 13-28 of U.S. Patent No. 6,942,654. Applicants do not concede the correctness of the rejection, however if the rejection remains when the claims are otherwise indicated as being allowable, Applicants will file a Terminal Disclaimer.

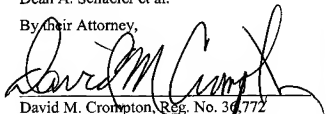
Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,



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